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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/672,891 | 09/26/2003 | Jonathan S. Stinson | 10527-450001/ 02-303 | 9546 |

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| EXAMINER | |
|---|---|
| ROE, JESSEE RANDALL | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1742 | |

DATE MAILED: 12/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/672,891 | STINSON, JONATHAN S. | |
| | Examiner | Art Unit | |
| | Jessee Roe | 1742 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *21 September 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-40* is/are pending in the application.

4a) Of the above claim(s) *23-40* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *26 September 2003* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *See Continuation Sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :26 November 2003, 13 May 2004 and 4 March 2005.

## DETAILED ACTION

### *Claims Status*

Claims 1-22 are currently under examination. Claims 23-40 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected method for forming a stent, there being no allowable generic or linking claim. Election was made without traverse in the reply filed on 21 September 2006.

### *Drawings*

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: 66. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-9 and 15-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Stinson et al. (US 5,888,201).

In regards to claims 1, 6, 9 and 15, Stinson et al. ('201) disclose an expandable (i.e. balloon) stent with a tubular body (col. 2, lines 41-55). The tubular body is comprised of an alloy with 74 weight percent titanium, 13 percent niobium, and 13 weight percent zirconium (col. 4, line 51 - col. 6, line 50). The yield strength of the tubular body is 141 ksi (greater than 45 ksi).

In regards to the magnetic susceptibility of about +1 or less and the mass absorption coefficient of 1.9 $cm^2/g$ or more, Stinson et al. ('201) does not disclose these properties. However, these properties would be met by the inherent material properties of a titanium-zirconium alloy with the same composition. See MPEP 2112.01 I.

In regards to claim 2, Stinson et al. ('201) disclose that the titanium base alloy stent has an ultimate tensile strength of 150 ksi (col. 5, lines 1-20).

In regards to claims 3-5, Stinson et al. ('201) disclose an expandable (i.e. balloon) stent with a tubular body (col. 2, lines 41-55). The tubular body is comprised of an alloy with 74 weight percent titanium, 13 percent niobium, and 13 weight percent zirconium (col. 4, line 51 - col. 6, line 50). Stinson et al. ('201) do not disclose the percent strength to peak load/fracture, the percent tensile elongation, the magnetic susceptibility, or the mass absorption coefficient. However, these properties would be met by the inherent material properties of a titanium-niobium-zirconium alloy with the same composition. See MPEP 2112.01 I.

In regards to claim 7-8 and 16-18, Stinson et al. ('201) disclose an expandable stent with a tubular body (col. 2, lines 41-55). The titanium used to construct the stent is commercially pure titanium (col. 3, lines 32-62). This titanium would be alloyed with zirconium forming a stent with 68 weight percent titanium and 32 weight percent zirconium (col. 11, lines 1-25). A zirconium content of 1-29 weight percent may be added to the titanium alloy (col. 11, lines 1-40).

In regards to claim 19, Stinson et al. ('201) disclose a stent with a diameter (thickness) of 0.007 inch (col. 4, lines 51-68).

In regards to claim 20, Stinson et al. ('201) disclose a stent that is a tubular, implantable medical device (i.e. therapeutic agent) (col. 1, lines 1-10 and col. 2, lines 42-55).

Claims 1-8 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Duerig et al. (JP 11-042283).

In regards to claim 1, 6-8, and 12, Duerig et al. ('283) disclose an expandable stent with a tubular body (abstract). The tubular body is comprised of a titanium base alloy with 3-20 weight percent tantalum (claim 1).

In regards to the yield strength of greater than 45 ksi; the magnetic susceptibility of about +1 or less; and the mass absorption coefficient of 1.91 $cm^2/g$ or more, Duerig et al. ('283) do not disclose these properties. However, these properties would be met by the inherent material properties of a titanium-tantalum alloy with the same composition. See MPEP 2112.01 I.

In regards to claim 2-5, Duerig et al. ('283) disclose an expandable stent with a tubular body (abstract). Duerig et al. ('283) do not disclose the ultimate tensile strength, the percent strength to peak load/fracture, the percent tensile elongation, the magnetic susceptibility, or the mass absorption coefficient. However, these properties would be met by the inherent material properties of a titanium-tantalum alloy with the same composition. See MPEP 2112.01 I.

Claims 1-6, 13-14 and 22 are rejected under 35 U.S.C. 102(e) as being anticipated by Mayer (US Publication 2003/0009215).

In regards to claim 1, 6 and 13-14, Mayer ('215) discloses an expandable stent with a tubular body (abstract, Figs. 1-14, and [0028]). The tubular body is comprised of an alloy with 11.5 weight percent molybdenum, 6 weight percent zirconium, 4.5 weight percent tin, and the remainder titanium [0078].

In regards to the yield strength of greater than 45 ksi; the magnetic susceptibility of about +1 or less; and the mass absorption coefficient of 1.91 $cm^2/g$ or more,

Mayer ('215) does not disclose these properties. However, these properties would be met by the inherent material properties of a titanium-molybdenum-zirconium alloy with the same composition. See MPEP 2112.01 I.

In regards to claims 2-5, Mayer ('215) discloses an expandable stent with a tubular body (abstract, Figs. 1-14, and [0028]). The tubular body is comprised of an alloy with 11.5 weight percent molybdenum, 6 weight percent zirconium, 4.5 weight percent tin, and the remainder titanium [0078]. Mayer ('215) do not disclose the ultimate tensile strength, the percent strength to peak load/fracture, the percent tensile elongation, the magnetic susceptibility, or the mass absorption coefficient. However, these properties would be met by the inherent material properties of a titanium-molybdenum-zirconium alloy with the same composition. See MPEP 2112.01 I.

In regards to claim 22, Mayer ('215) discloses an expandable stent with a tubular body (abstract, Figs. 1-14, and [0028]). The tubular body is comprised of an alloy with 11.5 weight percent molybdenum, 6 weight percent zirconium, 4.5 weight percent tin, and the remainder titanium [0078]. The titanium-based alloy stent is deployed from a catheter [0079].

In regards to the yield strength of greater than 45 ksi; the magnetic susceptibility of about +1 or less; and the mass absorption coefficient of 1.91 $cm^2/g$ or more, Mayer ('215) does not disclose these properties. However, these properties would be met by the inherent material properties of a titanium-molybdenum-zirconium alloy with the same composition. See MPEP 2112.01 I.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over of Duerig et al. (JP 11-042283) in view of Steinemann et al. (US 4,040,129).

In regards to claim 10, Duerig et al. ('283) disclose an expandable stent with a tubular body (abstract). The tubular body is comprised of a titanium base alloy (claim 1).

Duerig et al. ('283) disclose an expandable stent made of a titanium base alloy, but Dueriget al. ('283) do not disclose an expandable stent with a zirconium composition of about 50%.

Steinemann et al. ('129) disclose a titanium-zirconium alloy for a surgical and dental implant with a zirconium content of about 50% (col. 4, lines 50-68 and Example 6). Titanium-zirconium alloys are extraordinarily corrosion resistant and do not create a chemical reaction that is harmful to a living system. (col. 3, line 46 – col. 4, line 68).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the composition of the expandable stent, as disclosed by Duerig et al. ('283), to comprise a zirconium composition of about 50%, as disclosed by Steinemann et al. ('129), in order to obtain a titanium-zirconium alloy that is extraordinarily corrosion resistant and that does not create a chemical reaction that is harmful to a living system, as disclosed by Steinemann et al. ('129) (col. 3, line 46 – col.

4, line 68).

Claims 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over of Duerig et al. (JP 11-042283) in view of "Thermomechanical Analysis OF Ti40Ta and Ti50Ta Alloys".

In regards to claim 10, Duerig et al. ('283) disclose an expandable stent with a tubular body (abstract). The tubular body is comprised of a titanium base alloy (claim 1).

Duerig et al. ('283) disclose an expandable stent made of a titanium base alloy, but Dueriget al. ('283) do not disclose an expandable stent with a tantalum composition of about 40% or more.

"Thermomechanical Analysis Of Ti40Ta and Ti50Ta Alloys" discloses a titanium base alloy with a tantalum composition of 40% or more (introduction). Titanium-tantalum alloys have excellent mechanical properties, biocompatibility with human tissue, and corrosion resistance (introduction).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the composition of the expandable stent, as disclosed by Duerig et al. ('283), to comprise a titanium composition of 40% or more, as disclosed by "Thermomechanical Analysis Of Ti40Ta and Ti50Ta Alloys", in order to obtain a titanium-tantalum alloy that has excellent mechanical properties, biocompatibility with human tissue, and corrosion resistance, as disclosed by "Thermomechanical Analysis Of Ti40Ta and Ti50Ta Alloys" (introduction).

Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Duerig et al. (JP 11-042283) in view of Kim (US 6,146,404).

Duerig et al. ('283) disclose an expandable stent with a tubular body that may be deployed from a catheter (abstract and [0026]). The tubular body is comprised of a titanium base alloy with 3-20 weight percent tantalum (claim 1). Duerig et al. ('283) also discloses that the maximum expandable diameter is 40 mm or less [0024].

Duerig et al. ('283) meet the claim limitations of claim 21 with the exception of an expandable member in addition to the stent.

Kim ('404) discloses a thrombus filter that may be used within a catheter (col. 1, line 10 - col. 2, line 20. An expanded thrombus filter may be used to allow the body's natural lysing process to dissolve blood clots (col. 2, lines 20-50).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the expandable stent with the catheter, as disclosed by Duerig ('283) with the expandable thrombus filter, as disclosed by Kim ('404), in order to allow the body's natural lysing process to dissolve blood clots, as disclosed by Kim ('404)(col. 2, lines 20-50).

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessee Roe whose telephone number is (571) 272-5938. The examiner can normally be reached on Monday-Friday 8 AM - 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Roy King can be reached on (571) 272-1244. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JR

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